

**REMARKS**

This Reply is intended to be completely responsive to the Final Office Action dated July 23, 2008.

**Status**

Claims 1-17 are pending in this Application.

Claims 1-17 stand rejected.

Independent claims 1 and 13 have been amended.

Applicant believes that the rejections raised by the Examiner have been addressed and the Application is in condition for allowance. Reconsideration and allowance of pending Claims 1-17 is respectfully requested.

**Examiner Interview Conducted October 10, 2008**

On October 10, 2008, Applicant's attorney conducted a telephone interview with Examiner Koharski during which the current amendments to independent claims 1 and 13 were discussed in view of the art of record. It is Applicant's understanding that the Examiner agrees that independent claims 1 and 13, as amended, overcome the rejections based upon Spievack et al., U.S. Patent No. 5,871,484, Wilcox et al., U.S. Patent No. 5,681,289, Chappius, U.S. Patent Publication No. 2001/021852, and Sasso et al., U.S. Patent Publication No. 2004/0225292.

**Claim Rejections – 35 U.S.C. § 112 ¶ 1**

On page 2 of the Detailed Action, the Examiner rejected claims 1 and 13 under 35 U.S.C. § 112 ¶ 1, as failing to comply with the written description requirement. The Examiner stated that "Applicant cites the specification ([0037]) in which the insert is mentioned as aligning or not aligning with the fenestrations, not completely blocking the fenestrations." Applicant respectfully asserts that, at the time the application was filed, the Applicant had possession of the

invention as recited in claims 1 and 13 as amended by the previous Amendment. See Application paragraph [0037] and claim 3 as originally filed. While Applicant has deleted the language from claims 1 and 13 that the Examiner initially found unacceptable under the written description requirement of 35 U.S.C. § 112 ¶ 1, the present amendments to claims 1 and 13 have been made to overcome the Examiner's rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) only, and, therefore, should not be considered as an admission of or agreement with the Examiner's rejection under 35 U.S.C. § 112 ¶ 1.

**Claim Rejections – 35 U.S.C. § 102(b)**

On page 3 of the Office Action, the Examiner rejected claims 1 and 13 as being anticipated by Spievack et al. Applicant has amended independent claims 1 and 13 to overcome the rejections based on Spievack et al.

Independent claim 1, as amended, recites a “device for delivering a substance to a bone” comprising, in combination with other elements, “an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations.” The amendment to claim 1 is supported by the application as originally filed. See e.g., Application, paragraph [0037]. Independent claim 13, as amended, recites a “device for delivering a substance to a bone” comprising, in combination with other elements, “an insert disposed inside the cannulated bone-screw shaft such that the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations.” The amendment to claim 13 is supported by the application as originally filed. See e.g., Application, paragraph [0033] and paragraph [0037].

As agreed to during the interview with Examiner Koharski, Spievack et al. does not identically disclose “an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations

align with the one or more bone-screw fenestrations such that the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations,” as recited in independent claim 1, and does not identically disclose “an insert disposed inside the cannulated bone-screw shaft such that the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations,” as recited in independent claim 13. In contrast, Spievack et al. discloses a “sponge 30” positioned within an “orthopedic screw 90” including “vias 94.” See col. 5, lines 58-65 and Fig. 12. As can be seen in Fig. 12, “sponge 30 can include top and bottom seals 35 to limit the dispersal of the biologically active substance to a particular region of the inner cavity 95.” See col. 6, lines 3-5. However, neither “sponge 30” nor any other element of Spievack et al. appears to be “an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations,” as recited in independent claim 1, or “an insert disposed inside the cannulated bone-screw shaft such that the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations,” as recited in independent claim 13.

In view of the amendments to independent claims 1 and 13 and the arguments set forth above, Applicant respectfully asserts that claims 1 and 13 are not anticipated by Spievack et al. under 35 U.S.C. § 102(b).

### **Claim Rejections – 35 U.S.C. § 103(a)**

Rejection of Claims 1-17 Under 35 U.S.C. § 103(a) as Obvious over Wilcox et al. in View of Sasso et al or Chappius

On pages 4-6 of the Office Action, the Examiner rejected claims 1-17 under 35 U.S.C. § 103(a) as unpatentable over Wilcox et al. in view of Sasso et al. or in view of Chappius.

Applicant has amended independent claims 1 and 13 to recite a combination of subject matter that Applicant believes is allowable under 35 U.S.C. § 103(a).

As agreed to during the interview with Examiner Koharski, neither Wilcox et al., Sasso et al., nor Chappius, disclose, teach, or suggest “an insert disposed inside the cannulated bone-screw shaft ... wherein the insert is movable between: a first position wherein none of the one or more insert fenestrations align with the one or more bone-screw fenestrations such that the insert substantially prevents material from entering the cannulated portion of the bone-screw through the one or more bone-screw fenestrations,” as recited in independent claim 1, or “an insert disposed inside the cannulated bone-screw shaft such that the insert prevents at least some material from entering the cannulated portion of the bone screw through all of the one or more bone-screw fenestrations,” as recited in independent claim 13. In contrast, Wilcox et al. discloses both “a sump or bladder 100” and “a sump or bladder 110” (both identified as inserts by the Examiner). See col. 9, lines 14-18, col. 10, lines 42-43, and Figs. 8-13. Sasso et al. discloses an “elongate guiding portion 14.” See e.g., Paragraph [0031] and Figs. 2 and 3. Chappius discloses an “anchor 10.” See e.g., Paragraph [0027] and Fig. 1. As such, neither Wilcox et al., Sasso et al., nor Chappius, disclose, teach, or suggest “a device for delivering a substance to a bone” as recited in independent claims 1 and 13.

Because the references cited by the Examiner fail to disclose, teach, or suggest at least one element of independent claim 1 and independent claim 13, as amended, Applicant respectfully asserts that the “device for delivering a substance to a bone” recited in independent claims 1 and 13, as amended, would not have been obvious in view of Wilcox et al., alone or in any proper combination with either Sasso et al. or Chappius under 35 U.S.C. § 103(a).

### **Conclusion**

Claims 1-17 are pending in the present Application. Claims 1 and 13 have been amended. Favorable reconsideration of the application, as amended, is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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